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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,687	02/10/2004	Gregory B. Altshuler	105090-0236	3813

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EXAMINER	
JOHNSON III, HENRY M	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,687	ALTSHULER ET AL.	
	Examiner	Art Unit	
	Henry M. Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *012805 020705*:
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

In paragraph 01, the word claim should be claims in lines 1 and 7.

In paragraph 01, the patent number is required for 09/996,662.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-9, 22-29 and 31-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-16 and 18-26 of copending Application No. 10/777020. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6, 9-15 and 17-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8, 9, 11-15, 18-21, 23-37 and 41-46 of copending Application No. 10/777022. Although the conflicting

claims are not identical, they are not patentably distinct from each other because they are an obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 7-33 and 35-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6, 7, 9-11, 13-17, 20-33 and 35-40 of copending Application No. 10/776686. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 7-12, 14-31, 33, 34 and 36-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5-7-10, 12-17, 20-28 and 30-34 of copending Application No. 10/776936. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant is advised that should claim12 be found allowable, claim 19 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Objections

The claims are objected to because of the following informalities: an applicator is claimed, yet the dependent claims cite an apparatus.

The word emitting in claim 4 should be emitter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15 and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite as it cannot be determined if the shape refers to a cross section of the bristle or the elongate dimension.

Claim 29 recites the limitation "the radiation emitting element" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 29, 31-35 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/06456 to Chen et al. Chen et al. teach an apparatus employing light therapy to treat oral conditions (abstract) including a mouthpiece that surrounds the teeth and gums (Fig. 2) that may be comfortably left inside a patient's mouth for extended times (page 2, lines 32-35) and is made from an elastomeric material such as silicone (page 5, line 8). This is interpreted as a compliant mouthpiece. The radiation source is disclosed as an LED, laser diode, gas discharge lamp or filament bulb (page 3, lines 30-32). The source may be mounted on the mouthpiece or located external to the mouthpiece with the radiation delivered via fiber optics (optical element). The means for delivery may include diffusing material (page 3, line 25). The optical fibers deliver the radiation in different directions (page 6, lines 13-15). Portions of the mouthpiece may be highly reflective (page 7, line 21). The sources mounted around the mouthpiece clearly radiate in different directions. Chen et al. incorporates by reference U.S. Patent 5,445,608 that teaches the use of either an internal or external array of light sources and allows use of LEDs or laser diodes operating at two or more wavelengths, and the ability to selectively activate the sources operating at a given wavelength or waveband as desired, so that the light at the different wavelengths ore wavebands is provided to the treatment site either sequentially or simultaneously from the light sources (Col. 8, lines 37-45. The sources may be controlled by monitoring the temperature rise of the tissue (diagnostic sensor) (Col. 8, line 8). The current regulation will control the power of the light source.

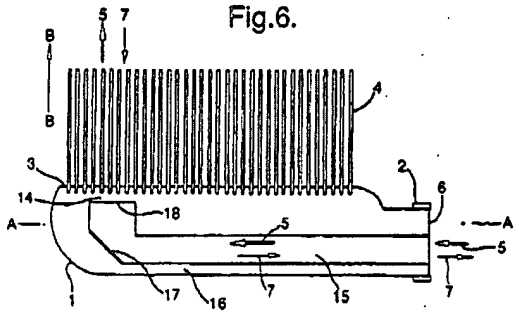
Regarding claims 5 and 6, the disclosure of a gas discharge source inherently produces a polychromatic radiation. Chen et al. teach specific wavelength for treatment and therefore it is

inherent that optical filters would be employed to obtain the desired wavelength or wavelengths when using a polychromatic source.

Regarding claims 8, 9, 33 and 34, the claims are directed to intended use.

Claims 1, 4, 7-12, 14, 16-19, 23 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,862,771 to Muller. Muller teaches a toothbrush with a head with bristles and a radiation source in a handle. The location in the handle is disclosed as convenient if the toothbrush is an electrical toothbrush, i.e. having electrical drive means to move the cleaning bristles in a tooth cleaning operation. The electric drive is interpreted as a vibrating mechanism. The radiation is directed in a direction parallel to the bristles either between the bristles or through the optically transparent bristles, thus teaching a plurality of emitters (Fig. 6). The bristles are interpreted as optical elements and capable of radiating in multiple directions as they are deflected during brushing. A reflecting surface directs the radiation to the bristles (Fig. 6, # 17). Along with the radiation source in the handle, a detector is disclosed for sensing reflected radiation. This detector is interpreted as a diagnostic sensor (Col. 2, lines 38-65). The apparatus is clearly capable of radiating any area within an oral cavity. The radiation source may be a light emitting diode (LED) of known type and filters and mirrors are disclosed in the optical path. The detection means and an appropriate power supply, electronic processing devices (control), and means to signal the presence and/or absence of biological deposits on a tooth surface may conveniently be provided within the handle of the toothbrush (Col. 8, lines 35-50). A lens may be used in the optical path (Col. 12, line 38) and this is interpreted as a diffuser as lenses may diverge a beam, effectively diffusing the beam. The bristles have a core made of

Fig.6.



a transparent plastic material, surrounded by a sheath also of a transparent plastic material with a lower refractive index than that of the core. Alternatively the sheath may be thin coating of a shiny metal, e.g. 2-3 microns thick (col. 13, lines 12-17). The head is disclosed as being detachable (Col. 8, line 55).

Regarding claims 16 and 17, Muller teaches radiation via the bristles inherently teaching their shape is appropriate and that they are lasing elements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller as applied to claim 19 above and further in view of U.S. Patent 6,273,884 to Altshuler et al. Muller is discussed above, but does not disclose inhibiting radiation when not in contact with tissue. Altshuler et al. teach a tissue treatment apparatus and the concept of total internal reflection. The optical delivery channel is treated to normally have total internal

reflection so that light or other radiation entering the channel is reflected internally, however, when lens (output face) is in contact with a patient's skin, the total internal reflection at the skin-contacting surface is broken due to the change of index of refraction at this surface so that light energy is emitted into the patient's skin (Col. 16, lines 25-33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the technique of modifying the index of refraction of the light channel as taught by Altshuler et al. in the invention of Muller to limit the radiation to the oral cavity as a safety consideration as suggested by Altshuler et al.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller as applied to claim 1 above, and further in view of U.S. Patent 6,029,303 to Dewan. Muller is discussed above, but does not teach the use of a motion sensor. Dewan teaches an electronic toothbrush with a handle, head, and bristles with a motion detector that activates a light or audio signal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the motion detector as taught by Dewan in the device of Muller to control or restrict the radiation to when the unit is in use.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller as applied to claim 1 above, and further in view of U.S. Patent 5,133,102 to Sakuma. Muller is discussed above, but does not teach the use of a contact sensor. Sakuma discloses an electronic toothbrush with a handle, head and bristles and a circuit that energizes a radiation device when the bristles contact the teeth, thus sensing contact and completing the circuit via the body of the user. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the contact sensor as taught by Sakuma in the device of Muller to activate the device when in the preferred use position, in contact with the oral tissue.

Claims 24, 26, 28 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller as applied to claim 1 above, and further in view of U.S. Patent 4,333,197 to Kuris. Muller is discussed above, but does not teach the use of heat sinks or ultrasonics, although the handle of Muller would inherently transfer heat from the radiation source in the handle to the rest of the device body and head because virtually all materials have some heat transfer capacity. Kuris teaches an ultrasonic toothbrush with a handle, head and bristles driven by ultrasonic frequencies (abstract). The handle is designed to remove the heat produces by the ultrasonic generator (Col. 4, lines 28-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the ultrasonic generator and heat removal techniques as taught by Kuris in the device of Muller to complement the hygienic process within an oral cavity.

Claims 25 and 27 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller in view of U.S. Patent 4,333,197 to Kuris as applied to claim 24 above, and further in view of U.S. Patent 6,350,276 to Knowlton. Muller and Kuris are both discussed above, but do not disclose cooling using fluids or phase changing substances. Knowlton discloses an apparatus for treating tissue using energy sources that may be light (Col. 7, lines 55-56). Figure 5, from a cross-referenced (and incorporated) Knowlton patent (6,425,912), teaches energy sources (Fig. 5, # 18) that conform to the skin. Knowlton teaches cooling of the sources and tissue using a liquid (Fig. 2B, # 15) that can be in a liquid or gaseous state, or may exist in two or more phases and may undergo a phase change as part of its cooling function (Col. 5, lines 29-35), such as melting or evaporation (whereby heat is absorbed by the fluid as a latent heat of fusion or evaporation). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the cooling methodologies as

taught by Knowlton et al. in the invention of Muller as modified by Kuris if the radiation sources require cooling as the fluid and phase change methods are common and known.

Claims 13 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller. Muller does not disclose the etching of a core cladding to diffuse the radiation. Scattering and diffusing are interpreted as equivalents. The practice of etching or otherwise modifying the refraction characteristics of a cladding to achieve a desired radiation effect or fluence is well known. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the etching technique to diffuse the radiation.

Claims 15, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/06456 to Chen et al. Chen et al. do not disclose the shaping the mouthpiece to include specific areas. It has been held that a change in the shape of a prior art device is a design consideration within the skill of the art. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). It would have been obvious to one having ordinary skill in the art at the time the invention was made to configure the mouthpiece as appropriate for the area to be treated.

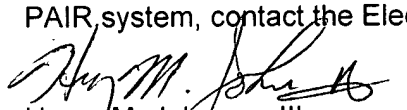
Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller as applied to claim 1 above, and further in view of U.S. Patent 5,658,148 to Neuberger et al. Muller is discussed above, but does not teach ports for delivery of agents via the device. Neuberger et al. teach a dental brush with an optical fiber (Fig. 2, # 21) that carries radiation from a radiation source and water or liquid passage (Fig. 2, # 22) that carries water or liquid under pressure to the brushhead (Col. 3, lines 25-28). The port is capable of delivering a drug. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include an agent delivery means as taught by Neuberger et al. in the invention of Muller as drug for use as photosensitizers are pervasive in the photodynamic therapy arts.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Henry M. Johnson, III
Patent Examiner
Art Unit 3739